



October 31, 2006

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
445 12th Street, S.W.
Washington, DC 20554

Re: ET Docket No. 06-135: RM-11271 - Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz

Dear Commission:

The American Association of People with Disabilities (AAPD)¹ is responding to the Commission's rulemaking in this matter. In particular, the Public Notice and Notice of Inquiry² stated the Commission was seeking comment on collaborative efforts between the Commission (FCC) and the U.S. Food and Drug Administration (FDA) regarding options for better educating device manufacturing industry leaders about medical radio device electromagnetic immunity issues in a radio frequency (RF) environment. On behalf of our members and persons with disabilities and their families, our comment addresses this topic and encourages the Commission to

¹ AAPD is the largest national nonprofit cross-disability member organization in the United States, dedicated to ensuring economic self-sufficiency and political empowerment for the more than 51 million Americans with disabilities. AAPD works in coalition with other disability organizations for the full implementation and enforcement of disability nondiscrimination laws, particularly the Americans with Disabilities Act (ADA) of 1990, the Rehabilitation Act of 1973, and other statutes, such as the Communications Act.

² July 13, 2006, by Notice of Proposed Rulemaking, Notice of Inquiry, and Order (FCC 06-103). ET Docket Nos. 06-135, 05-213, 03-92, and RM-11271; and FCC 06-103, Notice Of Proposed Rulemaking, Notice Of Inquiry, And Order, adopted July 13, 2006,

ensure consumer involvement in regard to rules for medical device radio communications service. Our specific recommendations follow:

In Paragraph 47, FCC requests input on how the FCC and the FDA could improve their collaborative efforts to provide education around electromagnetic interference issues. AAPD believes it to be very positive that officials of both agencies meet periodically to discuss matters of concern. However, we believe it would provide greater benefit if these meetings included FDA representatives from the Center for Devices and Radiological Health (CDRH) who are more closely involved with active implantable medical device approvals and who are familiar with issues specific to these devices.

Paragraph 47 also asks whether it would be beneficial to provide an FCC web site on which manufacturers or the general public could find informational documents on RF allocation and immunity issues or where problems of interference between medical radio devices and other radiocommunication devices could be reported. AAPD fully supports the creation of such a website so that consumers can be well-informed, for example, through the use of Fact Sheets, FAQs and summaries of regulations in Plain English.

We also support the creation of a website where consumers and others could report interference and similar concerns by means of an online form or a downloadable PDF form. AAPD also recommends that the FCC create an informal consumer complaint process -- similar to the one used for reporting telecommunications concerns (i.e., FCC Form 475) -- so that there is an opportunity for fast resolution of consumer concerns. This may also function as an “early warning system” of possible emerging concerns/difficulties, such as a commonly-experienced interference problem. While AAPD does not expect that there would be many of these complaints, such a system could be informative to both industry and government.

Furthermore, in response to Paragraph 48, we suggest that it would be beneficial to have a body comprising FCC officials and FDA officials, a liaison or representative from the active implantable medical device industry, as well as a consumer representative (s) from organizations that represent the users of devices. Such a group could develop appropriate communications and educational materials and programs, as needed. AAPD would be pleased to assist in facilitating consumer representation and the distribution of any developed materials.

AAPD recommends that the Commission's medical radio device rules cross-reference related FDA rules so that interested persons understand the relationship and scope of requirements. This is likely to help create awareness amongst manufacturers of the approvals they must obtain before distributing or selling medical radio devices. AAPD suggests easy-to-understand plain language Fact Sheets and FAQs aimed at informing consumers and the industry so that regulatory information is readily available for distribution throughout the medical industry and to consumers.

As the numbers of both medical device and emitters applications grow, AAPD believes our recommendations will facilitate beneficial communication about technological trends and consumer topics to the FCC and FDA, allowing these agencies to address, in a more consumer responsive way, compatibility and successful operation of medical devices in a changing electromagnetic frequency environment.

Thank you for the opportunity to present our recommendations. If further information is needed, please contact me at AAPD at (202) 457-0046, Extension 31.

Sincerely,

Jenifer Simpson

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